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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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09/435,504

11/06/1999

DENNIS SUNGA FERNANDEZ

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EXAMINER

MORGAN, ROBERT W

ART UNIT

PAPER NUMBER

3626

MAIL DATE

DELIVERY MODE

06/25/2008

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 09/435,504	Applicant(s) FERNANDEZ, DENNIS SUNGA	
	Examiner Robert W. Morgan	Art Unit 3626	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 28 March 2008.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-12 and 21-28 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-12 and 21-28 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Notice to Applicant

1. This communication is in response to the amendment filed 3/28/08, the following has occurred: Claims 1, 21 and 26-28 have been amended. Claims 1-12 and 21-28 are presented for examination.

Claim Rejections - 35 USC § 112

2. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1, 21 and 26-28 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The phrase "...his or her personal genetic nucleotide and protein folding structure..." renders the claim vague and indefinite. In particular, regarding the recitation of the patient's personal "protein folding structure" and "genetic nucleotide...profile", it is unclear whether Applicant intends to simply utilize general genetic marker information and unrelated protein data or if Applicant intends to indicate that a functional relationship between a specific gene sequence and the directly associated/attributionable protein changes is to be applied. In other words, it is unclear whether Applicant intends to utilize the two data sets independently or if Applicant is concerned with the functional relationship between the two. Accordingly, the relationship between the recited nucleotide sequence and the recited protein folding structure is unclear. Furthermore, while it is clear that the nucleotide sequence is "personal" and specific to the patient, it is unclear whether "protein folding structure" is personal and specific to the patient as if derived from an actual biological sample taken from the patient,

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or whether it is derived from the nucleotide sequence by computer modeling or other technique. For purposes of applying art, Examiner assumes Applicant intends to broadly encompass access permissions to all protein information and all nucleotide sequence information, in a general sense, and that the collective data to be accessed are limited and defined solely by the "voluntary-selection" step. However, appropriate clarification is requested.

Claim Rejections - 35 USC § 102

3. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 1, 27 and 28 rejected under 35 U.S.C. 102(e) as being anticipated by U.S. Patent No. 6,640,211 to Holden, for the same reasons indicated in the Board Decision mailed 3/6/06.

Further reasons appear below.

Claim 1, 27, and 28 has been amended to now recite "...and protein folding structure"

As per this limitation, Holden teaches that its profiles by genetic banking and testing services that are provided, and can include genotyping and bioinformatic profiling of general and or specific genetic marker panels (see: column 3, line 31-47).

Claim Rejections - 35 USC § 103

4. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 10-12, 21 and 23-26 are rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent No. 6,640,211 to Holden, for the same reasons indicated in the Board Decision mailed 3/6/06. Further reasons appear below.

Claim 21 and 26 has been amended to now recite "...and protein folding structure".

As per this limitation, Holden teaches that its profiles by genetic banking and testing services that are provided, and can include genotyping and bioinformatic profiling of general and or specific genetic marker panels (see: column 3, line 31-47).

Claims 2-4, 6-9 and 22 are rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent No. 6,640,211 to Holden in view of "Genetic Tests: Evolving Policy Question" by Asch, for the same reasons indicated in the Board Decision mailed 3/6/06.

Claim 5 is rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent No. 6,640,211 to Holden in view of U.S. Patent No. 6,275,824 to O'Flaherty, for the same reasons indicated in the Board Decision mailed 3/6/06.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Robert W. Morgan whose telephone number is (571) 272-6773. The examiner can normally be reached on 8:30 a.m. - 5:00 p.m. Mon - Fri.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, C. Luke Gilligan can be reached on (571) 272-6770. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

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/Robert Morgan/
Primary Examiner, Art Unit 3626